



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2019-D-1266]

Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of an immediately in effect guidance for industry entitled “Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds.” This document states the intent of FDA to exercise enforcement discretion regarding the requirements of the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” regulation (Produce Safety Regulation) as they apply to entities growing, harvesting, packing, and holding hops, wine grapes, pulse crops, and almonds.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2019-D-1266 for "Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or

Holding Hops, Wine Grapes, Pulse Crops, and Almonds: Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket

number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance. FOR FURTHER INFORMATION CONTACT: Fazila Shakir, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1355.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled “Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds.” We are issuing the guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. In accordance with § 10.115(g)(2), we are implementing the guidance immediately because we have determined that prior public participation is not feasible or appropriate. Although the guidance document is immediately in effect, FDA will accept comments at any time. The guidance is not subject to Executive Order 12866.

The FDA Food Safety Modernization Act (Pub. L. 111-353) directs FDA to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety. The Produce Safety Regulation is a set of science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. Produce is subject to the Produce Safety Regulation unless it is “not covered” or is eligible for an exemption. Produce that is not covered by the Produce Safety Regulation includes that which is rarely consumed raw (21 CFR 112.2(a)(1)), produced for personal or on-farm consumption (21 CFR 112.2(a)(2)), or not a raw agricultural commodity (21 CFR 112.2(a)(3)).

Following the publication of the final rule establishing the Produce Safety Regulation, FDA received feedback from some stakeholders that certain covered commodities--hops, wine grapes, pulse crops, and almonds--should be exempt from the requirements of the Produce Safety Regulation. After conducting an initial review of how hops, wine grapes, pulse crops, and almonds are grown, harvested, packed, held, and used, FDA has decided to exercise enforcement discretion with respect to the Produce Safety Regulation for entities growing, harvesting, packing, or holding those commodities while we consider pursuing rulemaking to address the unique circumstances they each present. This means that we will not expect entities growing, harvesting, packing, or holding these commodities to meet any of the Produce Safety Regulation requirements with respect to these commodities.

We will consider revising our intent to exercise enforcement discretion if, for example, new information becomes available regarding safety concerns associated with the production and consumption of these commodities.

## II. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: March 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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